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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,519	06/22/2007	Dieter Manstein	036213/US/3 - 475387-290	1188
30873 7590 07/06/2010 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177			EXAMINER BUCKLEY, AUDREA	
			ART UNIT 1611	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,519	Applicant(s) MANSTEIN, DIETER	
	Examiner AUDREA J. BUCKLEY	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-13, 16, 17 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 16, 17, and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>(2) 4/4/08; 10/18/08</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-9, 11-13, 16, 17, and 20-25 are pending and examined on the merits herein.

Priority/Benefit

This application is a 371 of PCT/US05/11338, filed 4/1/2005 which claims benefit of 60/558,476, filed 4/1/2004. The certified copy of the priority document has been received.

Information Disclosure Statement

The information disclosure statements (IDS) (2) submitted on 4/4/08 and 10/18/08 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

As to the IDS submitted 4/4/08, it is noted that the foreign documents and non-patent literature documents are not present in the instant application file or the file of provisional application 60/558,476. For this reason, it has been indicated on the IDS that these references were not considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by
Anderson et al. (US 2003/015965 A1, filed Mar. 2003).**

Anderson et al. teach permanent and removable tissue markings designed in advance for change and/or removal on demand; these markings are implemented by applying specific energy such as electromagnetic radiation to the tissue marking site where colored microparticles have been implanted (see abstract, in particular). Regarding claim 1, Anderson et al. teach that chromophores (see paragraphs [0087]-[0091]) are applied as tissue markings in the skin by implantation (see [0131], [0133], and [0136]). It is noted that this implantation process necessarily requires the application to a predetermined area of skin a specific pattern of fractional wounding as in the first method step of pending claim 1. Anderson et al. further teach the subsequent selective change and/or removal of these tissue marking microparticles can be applied (see [0044] and [0032]) by exposure to a specific type of electromagnetic energy (radiation) (see [0142]). Anderson et al. teach that this selective change is a predetermined removal method which may be employed for changing or removing a tissue marking [0044]). Therefore, Anderson et al. teach the method steps of the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4, and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/015965 A1, filed Mar. 2003).

The teachings of Anderson et al. are delineated above with respect to claim 1.

As to claim 2, Anderson et al. do not teach a particular embodiment of the invention in which the chromophore is applied as a layer; therefore this rejection of claim 2 is made using obviousness rationale. However, Anderson et al. explicitly teach that the inks can be implanted using a non-invasive method such as one which is well-suited to create an even tone of pigment over a relatively large body surface area (therefore, a layer) such as in the application of a removable sun tan (see [0132]). Therefore, one of ordinary skill in the art at the time the invention was made would have found the layered application of a chromophore to have been obvious based on Anderson's suggestion of applying an even tone of pigment over a relatively large body surface area. One would

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have been motivated to utilize this method step in order to create a removable sun tan, per Anderson's suggestion.

As to claim 3, Anderson et al. teach that incomplete removal can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered (see [0158] and Example 3 [0173]). Because it is not certain that Anderson et al. employed this method of fluence adjustment and pulse number adjustment, this rejection is made using obviousness rationale. Nonetheless, one reasonably would have expected continued success from the incomplete removal as adjusted by one of ordinary skill in the art as taught by Anderson.

As to claim 4, Example 3 [0169] further teaches that the microparticulate chromophores are prepared by grinding dry powdered Rose Bengal and sifting it to obtain uniform particles of a specified size to be implanted. Because it is not apparent that Anderson et al. implemented the powder as a dry powder, this rejection is made using obviousness rationale. However, since Anderson teaches the powder and the option to implement the powder as a suspension, it would have been obvious to one of ordinary skill that the option that the suspension was not a necessary form for the powder implementation. Therefore, one reasonably would have had the expectation of continued success upon the implantation of the powder form of the microparticulate chromophore (i.e., Rose Bengal as taught by Anderson).

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As to claims 6-9, Anderson et al. teach coating materials which include substances capable of encapsulating chromophores such as cyanoacrylate and Epo-Tek 301, an adhesive/structural glue, manufactured by Epoxy Technology, among others. Anderson et al. does not teach a particular embodiment of the invention employing Epo-Tek 301 (attachment medium, adhesive, glue); therefore, this rejection is made using obviousness rationale. Anderson et al. further teach that in some embodiments the coating is made of a material including specific absorption components that strongly absorb in a particular spectral region with the region from 800 to 1800 nm (light-activated) being most desirable [0080]). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement Epo-Tek 301, for instance, and/or a specific absorption component, in accordance with the teachings of Anderson. One would have been motivated to use Epo-Tek 301 in particular since Anderson teaches that these materials are biocompatible and approved by the FDA for use in medical devices (see [0121]), and one would have been motivated to use specific absorption (light-activated) components in order to control the release of the chromophores (see [0080]).

As to claim 22, Anderson et al. teach graphite (carbon) and carbon among the chromophore components (see [0023]) where graphite in particular is named among the examples of useful colored near-infrared absorbing materials [0095]). Anderson's Example 1 employs graphite particles in the chromophore microparticles (see [0162]).

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As to claim 23, Example 2 of Anderson teaches that yellow microparticles are ruptured by IR radiation (heat) (see [0165]). Therefore, Anderson teaches a yellow chromophore that undergoes a phase transition upon a change in temperature.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/015965 A1, filed Mar. 2003) as applied above, and further in view of Eppstein et al. (US 2002/0091311 A1, published Jul. 2002).

The teachings of Anderson et al. are delineated above.

As to claim 24, Anderson et al. teach waxes with a melting point substantially above body temperature (paraffin), for example, natural waxes, synthetic waxes, and mixtures, (see [0079] and [0113]). Anderson et al. does not teach any paraffin in particular.

However, Eppstein et al. teach methods for transporting substances across a biological membrane of an animal such as a human where openings in the biological membrane facilitate treatment applications, et cetera. Specifically, Eppstein et al. teach that the substrate may be designed to deliver pigments to effect an instantaneous tattoo application upon detonation of the pyrotechnic charges suitable for veterinary or cosmetic tattoos. The substrate may preferably be chosen from the suitable examples including paraffin, waxes, and other functional equivalents (see [0002] and [0044]).

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute paraffin in particular as taught by Eppstein et al. for the wax generally disclosed in Example 1 of Anderson et al. From this substitution of equivalents known for the same purpose, one of ordinary skill in the art at the time the invention was made reasonably would have expected continued success (see MPEP 2144.06) and would have been motivated to make this substitution since paraffin is a particular suitable material more specific than "wax" and explicitly taught to be useful for containing pigments for cosmetic tattoos (see [0044]).

Claims 5, 11-13, 16, 17, 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/015965 A1, filed Mar. 2003) as applied above and further in view of Mueller et al. (US 5,836,998, patented Nov. 1998).

The teachings of Anderson et al. are delineated above. Anderson et al. teach that the microparticles can be used to produce new cosmetic markings by addition to the tissue of and/or under the fingernails, for example, to create solid colors, patterns, or designs for decorative purposes [0138].

As to claims 5, 13, and 17, Anderson et al. do not teach the devices (i.e., stencil) for application as instantly recited. As to claims 11 and 16, Anderson et al. do not teach the application of a mask with a pattern where the pattern corresponds to the desired "fractional wounding" pattern.

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However, Mueller et al. teach a stencil for body art wherein the stencil allows a decorative stain to be applied to a predetermined epidermal area (see column 1, line 65 – column 2, line 11). As to claims 16 and 25, see Figure 1 in which the stencil design (a heart shape) allows for the application of color (chromophore) where the skin is not in contact with the mask.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the stencil pattern as taught by Mueller et al. for improved control of the chromophore application/removal pattern in the methods of Anderson et al. One would have been motivated to do so in order to minimize human error and to maximize control over the product design in its application, as taught by Mueller et al. (see column 2, lines 9-10).

As to claim 12, the stencils (masks) of Mueller et al. are applied to the skin (see column 3, lines 15-17).

As to claims 20 and 21, Anderson et al. teach chromophores including modern pigments of inorganic metal salts and brightly colored organometallic complexes [0006] which necessarily would act as chromophores, reflecting light and colors. Also, Anderson teaches silica and glass light reflectors as chromophore components Bis(diiminosuccino-nitrilo)metal complexes and silica are an example of these chromophores (see Anderson claim 35, for instance). Based on this teaching, one of ordinary skill in the art reasonably would have expected continued success from the implementation of the metal complex or silica chromophores taught by Anderson.

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As to claim 23, Anderson teaches that the chromophore may be thermolabile such that exposure of the microparticle to the specific energy heats and alters the chromophore (see [0023]).

Conclusion

No claims are found allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611